

Attorney's Docket No.: 00216-552001 / H-245 (Kay 32)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Peter Styczynski et al.

Art Unit : 1617

Serial No. : 09/893,252

Examiner : Lauren Q. Wells

Filed : June 27, 2001

Title : REDUCTION OF HAIR GROWTH

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

RECEIVED

OCT 20 2003

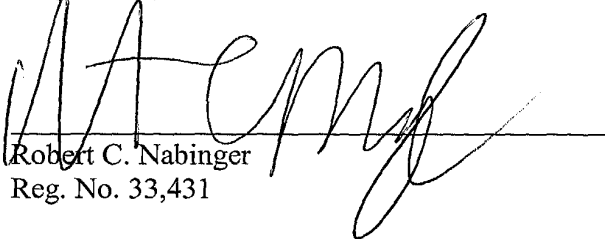
TECH CENTER 1000/2900

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the attached form PTO-1449. Copies of the Notification of Transmittal of the International Search Report and PCT Written Opinion in a counterpart application are also enclosed.

This filing is being made with the filing of a Request for Continued Examination. No fee is required.

Respectfully submitted,


Robert C. Nabinger
Reg. No. 33,431

Date: October 14, 2003

Fish & Richardson P.C.
225 Franklin Street
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Facsimile: (617) 542-8906

20736618.doc

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

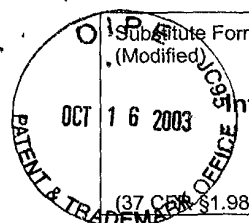
October 14, 2003

Date of Deposit


Signature

Sherry L. Hunt

Typed or Printed Name of Person Signing Certificate


 Substitute Form PTO-1449
 (Modified)

 U.S. Department of Commerce
 Patent and Trademark Office

 Attorney's Docket No.
 00216-552001

 Application No.
 09/893,252

**Information Disclosure Statement
 by Applicant**

(Use several sheets if necessary)

(37 CFR §1.98(b))

 Applicant
 Peter Styczynski et al.

 Filing Date
 June 27, 2001

 Group Art Unit
 1615

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,017,912	01/25/00	Bussell			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

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Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AL	WO 99/19466	04/22/99	PCT				
	AM	WO 98/23276	06/04/98	PCT				
	AN	9-143096	06/03/97	Japan (English Abstract Only)				
	AO							
	AP							

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AQ	
	AR	
	AS	
	AT	

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
LADAS & PARRY
Attn. Richards, John
26 West 61st Street
New York, NY 10023
UNITED STATES OF AMERICA

RECEIVED

AUG 12 2003

L & P.

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing (day/month/year)	07/08/2003
Applicant's or agent's file reference H-245	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US 02/18702	International filing date (day/month/year) 12/06/2002
Applicant THE GILETTE COMPANY	

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 20 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: 31-651-690-11 Telex: (+31-70) 2247016 	Authorized officer Nicolas Michaleczek
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Form PCT/ISA/220 (July 1998)

Buk sr

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/18702

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K7/00 A61K7/06 A61K31/19 A61K31/4745 A61K31/56
A61K48/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, BIOSIS, MEDLINE, EMBASE, PASCAL, SCI SEARCH

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 23276 A (GABEV EVGENI EVGENIEV ;ANRET LTD (BG); GABEV EVGENI BOGOMILOV (BG)) 4 June 1998 (1998-06-04) abstract	22,23,27
X	JP 09 143096 A (POLA CHEM IND INC) 3 June 1997 (1997-06-03) abstract	22,23,27
X	US 6 017 912 A (BUSSELL LETANTIA) 25 January 2000 (2000-01-25) abstract examples; claims	22,23,27
	<div style="text-align: center;"> <div>---</div> <div>---</div> <div>---</div> </div> <div style="text-align: right;">-/--</div>	

+ WO 99/19466

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

15 July 2003

Date of mailing of the international search report

07/08/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Hornich, E

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/18702

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>IZBICKA E ET AL: "Effects of cationic porphyrins as G-quadruplex interactive agents in human tumor cells." CANCER RESEARCH. UNITED STATES 1 FEB 1999, vol. 59, no. 3, 1 February 1999 (1999-02-01), pages 639-644, XP 002247791 ISSN: 0008-5472</p>	
A	<p>RAMIREZ RUBEN D ET AL: "Telomerase activity concentrates in the mitotically active segments of human hair follicles." JOURNAL OF INVESTIGATIVE DERMATOLOGY, vol. 108, no. 1, 1997, pages 113-117, XP009013613 ISSN: 0022-202X</p>	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 4, 5

1. The subject-matter of present claims 1, 19-21, 22, 25, 27 and 28 (and the dependent claims 3-18) is defined by means of the functional features 'inhibitor of telomerase', 'a compound that reduces telomerase levels in the hair follicles', 'a compound that reduces telomerase mRNA expression in the hair follicles', 'a compound that promotes the erosion of telomeric DNA in the hair follicles'.

Because of the character of the functional features, it cannot be guaranteed that the performed search is complete.

It cannot be excluded that compounds fulfilling the requirements of the functional feature have not been identified as doing so in the prior art. If such compounds have not been identified in the application either, they have not been covered by the search.

The search has been carried out, based on the functional features per se as well as the examples given in the application and the compounds particularly mentioned in claim 2.

It is further pointed out that the substantive examination can only be carried out to the same extent as the search.

2. Present claims 4 and 5 relate to the use of a composition which is defined by reference to a desirable characteristic or property. An attempt is made to define the composition by reference to a result to be achieved and thus is unclear in the sense of Art. 6 PCT.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 4, 5

1. The subject-matter of present claims 1, 19-21, 22, 25, 27 and 28 (and the dependent claims 3-18) is defined by means of the functional features 'inhibitor of telomerase', 'a compound that reduces telomerase levels in the hair follicles', 'a compound that reduces telomerase mRNA expression in the hair follicles', 'a compound that promotes the erosion of telomeric DNA in the hair follicles'.

Because of the character of the functional features, it cannot be guaranteed that the performed search is complete.

It cannot be excluded that compounds fulfilling the requirements of the functional feature have not been identified as doing so in the prior art. If such compounds have not been identified in the application either, they have not been covered by the search.

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The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 02/18702

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 1-21, 24 and 28 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 4, 5
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/18702

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9823276	A	04-06-1998	AU 4937097 A	22-06-1998
			WO 9823276 A2	04-06-1998
			BG 101011 A	29-05-1998
JP 09143096	A	03-06-1997	NONE	
US 6017912	A	25-01-2000	NONE	

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

Richards, John
LADAS & PARRY
26 West 61st Street
New York, NY 10023
ETATS-UNIS D'AMERIQUE

RECEIVED
AUG 27 2003
L. & P.

WRITTEN OPINION
(PCT Rule 66)

Date of mailing
(day/month/year) 21.08.2003

Applicant's or agent's file reference
H-245

REPLY DUE within 1 month(s)
from the above date of mailing

International application No.
PCT/US02/18702

International filing date (day/month/year)
12.06.2002

Priority date (day/month/year)
27.06.2001

International Patent Classification (IPC) or both national classification and IPC
A61K7/00

Applicant
THE GILLETTE COMPANY et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:

I	<input checked="" type="checkbox"/>	Basis of the opinion
II	<input type="checkbox"/>	Priority
III	<input checked="" type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input type="checkbox"/>	Lack of unity of invention
V	<input checked="" type="checkbox"/>	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/>	Certain documents cited
VII	<input type="checkbox"/>	Certain defects in the international application
VIII	<input type="checkbox"/>	Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 27.10.2003

Name and mailing address of the international preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Hornich, E

Formalities officer (incl. extension of time limits)

Morancho Alcaine, N

Telephone No. +49 89 2399-7362



ENTERED BY
CENTRAL
ACTION

ENTRY WD

Ext WD JR

9/21/03

WRITTEN OPINION

International application No. PCT/US02/18702

I. Basis of the opinion

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*):

Description, Pages

1-9 as originally filed

Claims, Numbers

1-28 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this opinion.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

WRITTEN OPINIONInternational application No. **PCT/US02/18702**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 1-22, 24, 25, 27, 28;

because:

- ☒ the said international application, or the said claims Nos. 1-21, 24, 28 (with regard to industrial applicability) relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the said claims Nos. 4, 5; 1, 3-22, 25, 27, 28 (partly)
2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the Standard.
- ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-3, 6-21, 24 (yes); 22, 23, 25-28 (no)
Inventive step (IS)	Claims	1-3, 6-21, 22-28 (no)
Industrial applicability (IA)	Claims	22, 23, 25-27 (yes)

2. Citations and explanations

see separate sheet

SECTION III

1. The IPEA will only formulate an assessment of novelty, inventive step and industrial applicability for the *parts of the present claims for which an International Search Report has been drawn up (R. 66.1(e) PCT)*(cf. form PCT/ISA/210, Box I), i.e. claims 1, 3-22, 25, 27 and 28 partly.
2. Claims 1-21, 24 and 28 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).
3. The subject-matter of claims 4 and 5 is unclear as relating to a *result to be achieved*, thus not fulfilling **R. 6.3 PCT** defining that 'claims shall define the matter for which protection is sought in terms of the technical features of the invention'.

SECTION V *with regard to item 1.*

4. References:

D1: WO 98 23276 A

D2: JP 09 143096 A

D3: US-A-6 017 912

D4: IZBICKA E ET AL: 'Effects of cationic porphyrins as G-quadruplex interactive agents in human tumor cells.' CANCER RESEARCH. UNITED STATES 1 FEB 1999, vol. 59, no. 3, 1 February 1999 (1999-02-01), pages 639-644, ISSN: 0008-5472.

~~D5: RAMIREZ RUBEN D ET AL: 'Telomerase activity concentrates in the mitotically active segments of human hair follicles.' JOURNAL OF INVESTIGATIVE DERMATOLOGY, vol. 108, no. 1, 1997, pages 113-117, ISSN: 0022-202X.~~

It is furthermore made reference to the following document which was not cited in the International Search Report; a copy is adhered to the Written Opinion:

D6: WO 99/19466

5. Novelty (Art. 33(2) PCT) *with regard to item 1.*

- 5.1 It would appear that the use of telomerase inhibitors and in particular the compounds listed in claim 2 for the preparation of a *dermatologically acceptable composition* for the application to an area of skin for the reduction of hair growth has not yet been disclosed within the prior art.

Novelty could thus be acknowledged for the subject-matter of claims 1-3, 6-21 and 24.

- 5.2 *Novelty* can however **not** be acknowledged for the subject-matter of claims 25, 26 and 28:

D6 discloses nucleoside analogues, among them for instance AZT which may be administered to destroy hair follicles (as a depilatory reagent) (p. 32, l. 9 and 24-29).

AZT is listed as telomerase inhibitor in the present claim 2, and therefore D6 would **anticipate** the subject-matter of claims 25, 26 and 28.

- 5.3 D1, D2, D3 and D6 disclose pharmaceutical compositions comprising compounds selected from those defined in claim 2.

The subject-matter of claims 22, 23 and 27 can thus **not** be regarded **novel**.

6. Inventive Step (Art. 33(3) PCT) **with regard to item 1.**

D6 discloses the usefulness of AZT which is listed as telomerase inhibitor in the present claim 2 to destroy hair follicles (as a depilatory reagent).

The subject-matter of claims 1-3, 6-21 and 24 would **not** appear to be of such significance as to support an **inventive step**.

7. Industrial Applicability (Art. 33(4) PCT) **with regard to item 1.**

- 7.1 For the assessment of the present claims 1-21, 24 and 28 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/US02/18702

a compound for the manufacture of a medicament for a new medical treatment.

- 7.2 The requirements of industrial applicability would be fulfilled for the subject-matter of claims 22, 23, 25-27.